



## **ENVIRONMENTAL PROTECTION AGENCY**

**[EPA-HQ-ORD-2023-0435; FRL-11277-01-ORD]**

### **Call for Information on the Integrated Science Assessment for Ozone and Related**

#### **Photochemical Oxidants**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice; call for information.

**SUMMARY:** The Environmental Protection Agency (EPA) is preparing an Integrated Science Assessment (ISA) as part of the review of the air quality criteria and the primary (health-based) and secondary (welfare-based) National Ambient Air Quality Standards (NAAQS) for Ozone (O<sub>3</sub>) and related photochemical oxidants. The ISA will be developed by the Center for Public Health and Environmental Assessment (CPHEA) within EPA's Office of Research and Development. When final, the ISA is intended to update the previous ISA for O<sub>3</sub> and related photochemical oxidants (EPA/600/R-20/012), published in 2020. Interested parties are invited to assist EPA in developing and refining the scientific information base for the review of the O<sub>3</sub> NAAQS by submitting research studies and data that have been published or accepted for publication since January 1, 2018.

**DATES:** All communications and information should be received by EPA by **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

**ADDRESSES:** Information may be submitted electronically, by mail, by facsimile, or by hand delivery/courier. Please follow the detailed instructions as provided in the section of this notice entitled **SUPPLEMENTARY INFORMATION**.

#### **FOR FURTHER INFORMATION CONTACT:**

For information on the public comment period, contact the ORD Docket at the EPA

Headquarters Docket Center; phone: 202-566-1752; facsimile: 202-566-9744; or email:

[ord.docket@epa.gov](mailto:ord.docket@epa.gov). For technical information, contact Qingyu Meng; phone: 919-541-2563; or

email: meng.qingyu@epa.gov; or Jeffrey Herrick; phone: 919-541-7745; or email:

herrick.jeffrey@epa.gov.

## **SUPPLEMENTARY INFORMATION:**

### *I. Information About the Document*

Section 108(a) of the Clean Air Act (the Act) directs the Administrator to identify and list certain air pollutants which, among other things, “cause or contribute to air pollution which may reasonably be anticipated to endanger public health or welfare;”<sup>1</sup> and then to issue air quality criteria for them. The air quality criteria are to “accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of [the] pollutant in the ambient air....”.

Under section 109 of the Act, EPA is then to establish NAAQS for each pollutant for which EPA has issued criteria. Section 109(d)(1) of the Act additionally requires periodic review and, if appropriate, revision of existing air quality criteria to reflect advances in scientific knowledge on the effects of the pollutant on public health and welfare. Under the same provision, EPA is also to periodically review and, if appropriate, revise the NAAQS, based on the revised air quality criteria. Documents and technical materials associated with NAAQS reviews are available at <https://www.epa.gov/naaqs>.

Photochemical oxidants, including O<sub>3</sub>, are one of six “criteria” pollutants for which EPA has established NAAQS, and O<sub>3</sub> is the current indicator for that NAAQS. In its periodic review of the air quality criteria for these pollutants, EPA reviews the currently available science and prepares an ISA. The ISA provides the scientific foundation for EPA’s NAAQS reviews, in conjunction with additional technical and policy assessments, and for the Administrator’s decisions on the adequacy of the current NAAQS and the appropriateness of possible alternative

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<sup>1</sup> Under Clean Air Act section 302(h), welfare effects include, but are not limited to, “effects on soils, water, crops, vegetation, manmade materials, animals, wildlife, weather, visibility, and climate, damage and deterioration of property, and hazards to transportation, as well as effects on economic values and on personal comfort and well-being.”

standards. Early steps in this review process include announcing the initiation of the review of the air quality criteria and the NAAQS and the intention of the EPA to develop an ISA, and requesting that the public submit scientific literature that they want to bring to the attention of the Agency as it begins this process. The Clean Air Scientific Advisory Committee (CASAC), whose review and advisory functions are mandated by section 109(d)(2) of the Clean Air Act, is charged, among other things, with the independent scientific review of the air quality criteria. In conjunction with the CASAC review, the public will have an opportunity to review and comment on the draft ISA. The ISA developed in this review of the air quality criteria and O<sub>3</sub> NAAQS will build on the scientific assessment from the last review,<sup>2</sup> focusing on assessing and integrating the information newly available since that considered in the 2020 ISA. With regard to development of the ISA, the public is encouraged to assist in identifying relevant scientific information for the review by submitting research studies that were not part of the prior review, and that have been published or accepted for publication in a peer-reviewed journal. The Agency is interested in obtaining newly available information, particularly concerning toxicological studies of effects of controlled exposure to O<sub>3</sub> in laboratory animals, humans, and *in vitro* systems; epidemiologic (observational) studies of health effects associated with ambient O<sub>3</sub> exposures in human populations; studies examining populations and life stages that may be at increased risk of O<sub>3</sub>-related health effects. For studies examining effects on welfare or the environment, studies that address or provide new information on terrestrial biota are of particular interest, including effects of O<sub>3</sub> on vegetation; communities and populations of plants and associated biota, as well as exposure-response relationships between O<sub>3</sub> in ambient air and specific welfare effects. The EPA also seeks recent information in other areas of O<sub>3</sub> research such as atmospheric chemistry and physics, sources and emissions, analytical methodology, transport and transformation in the environment, and ambient concentrations.

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<sup>2</sup> The scientific assessment for the last review is documented in the Integrated Science Assessment (ISA) for Ozone and Related Photochemical Oxidants (Final Report, April 2020). U.S. Environmental Protection Agency, Washington, DC, EPA/600/R-20/012, 2020; 85 FR 21849, April 20, 2020.

The Agency also seeks information regarding the design and scope of the review of the air quality criteria to ensure that it addresses key policy-relevant issues and considers the new science that is relevant to informing our understanding of these issues. The Agency seeks new scientific information that may address key uncertainties identified in the last O<sub>3</sub> NAAQS review, which are provided in section 3.6 of the 2020 Policy Assessment (EPA-452/R-20-001, May 2020).<sup>3</sup> The Agency also seeks new scientific information or data that may address scientific and technical issues raised in two more recent letters from CASAC: one dated November 22, 2022 (EPA-CASAC-23-001)<sup>4</sup> and the other dated June 9, 2023 (EPA-CASAC-23-002).<sup>5</sup> Other opportunities for submission of new peer-reviewed, published (or in-press) papers will be possible as part of public comment on the draft ISA that will be reviewed by the CASAC.

## *II. How to Submit Technical Comments to the Docket at [www.regulations.gov](http://www.regulations.gov)*

Submit your materials identified by Docket ID No. EPA-HQ-ORD-2023-0435 by one of the following methods:

- [www.regulations.gov](http://www.regulations.gov): Follow the on-line instructions for submitting comments.
- E-mail: [ord.docket@epa.gov](mailto:ord.docket@epa.gov)
- Mail: U.S. Environmental Protection Agency, EPA Docket Center, Office of Research and Development Docket, Mail Code 28221T, 1200 Pennsylvania Avenue, NW, Washington, DC 20460. The phone number is 202-566-1752.
- Hand Delivery or Courier: EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Avenue, NW, Washington, DC 20004. The Docket Center's hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday (except Federal holidays). If you

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<sup>3</sup> The 2020 Policy Assessment for the Review of the Ozone National Ambient Air Quality Standards is available at: [https://www.epa.gov/sites/default/files/2020-05/documents/o3-final\\_pa-05-29-20compressed.pdf](https://www.epa.gov/sites/default/files/2020-05/documents/o3-final_pa-05-29-20compressed.pdf)

<sup>4</sup> Letter from Elizabeth A. Sheppard, Chair, Clean Air Scientific Advisory Committee, to Administrator Michael S. Regan. Re: CASAC Review of the EPA's Integrated Science Assessment (ISA) for Ozone and Related Photochemical Oxidants (Final Report - April 2020). November 22, 2022. EPA-CASAC-23-001. Available at: [https://casac.epa.gov/ords/sab/f?p=105:18:8476900499267::RP,18:P18\\_ID:2614](https://casac.epa.gov/ords/sab/f?p=105:18:8476900499267::RP,18:P18_ID:2614).

<sup>5</sup> Letter from Elizabeth A. Sheppard, Chair, Clean Air Scientific Advisory Committee, to Administrator Michael S. Regan. Re: CASAC Review of the EPA's Policy Assessment (PA) for the Reconsideration of the Ozone National Ambient Air Quality Standards (External Review Draft Version 2) (June 9, 2023) (EPA-CASAC-23-002). Available at [https://casac.epa.gov/ords/sab/f?p=113:18:7093179574667::RP,18:P18\\_ID:2636#meeting](https://casac.epa.gov/ords/sab/f?p=113:18:7093179574667::RP,18:P18_ID:2636#meeting).

provide materials by mail or hand delivery, please submit three copies of these materials. For attachments, provide an index, number pages consecutively with the materials, and submit an unbound original and three copies.

*Instructions:* Direct your comments to Docket ID No. EPA-HQ-ORD-2023-0435.

Please ensure that your comments are submitted within the specified comment period.

Comments received after the closing date will be marked “late,” and may only be considered if time permits. It is EPA's policy to include all materials it receives in the public docket without change and to make the materials available online at [www.regulations.gov](http://www.regulations.gov), including any personal information provided, unless materials include information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through [www.regulations.gov](http://www.regulations.gov) or e-mail. The [www.regulations.gov](http://www.regulations.gov) website is an “anonymous access” system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail directly to EPA without going through [www.regulations.gov](http://www.regulations.gov), your e-mail address will be automatically captured and included as part of the materials that are placed in the public docket and made available on the Internet. If you submit electronic materials, EPA recommends that you include your name and other contact information in the body of your materials and with any disk or CD-ROM you submit. If EPA cannot read your materials due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider the materials you submit. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA’s public docket visit EPA’s Docket Center homepage at <https://www.epa.gov/dockets>.

*Docket:* Documents in the docket are listed in the [www.regulations.gov](http://www.regulations.gov) index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other materials, such as copyrighted material,

are publicly available only in hard copy. Publicly available docket materials are available either electronically in [www.regulations.gov](http://www.regulations.gov) or in hard copy at the ORD Docket in EPA's Headquarters Docket Center.

**Wayne Cascio,**  
*Director,*  
*Center for Public Health and Environmental Assessment.*

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